K112543

DEC 2 9 2011

SECTION 5
510(k) SUMMARY

1. Submitter

Boston Scientific Corporation
100 Boston Scientific Way
Marlborough, MA 01752
Telephone: 508-683-4454
Fax: 508-683-5939

Contact: Thomas Hirte
Senior Manager Regulatory Affairs
Date Prepared: August 04, 2011

2. Device

Trade Name:	WallFlex™ Biliary Transhepatic Stent System
Common Name:	Biliary Stent system
Classification Name:	Biliary catheter and accessories
Regulation Number:	876.5010
Product Code:	FGE
Classification:	Class II

3. Predicate Devices

The Boston Scientific Corporation, Wallstent Transhepatic Biliary Endoprosthesis (K964119), the Boston Scientific Corporation, Wallstent Biliary Endoprosthesis (K000308, K993232) , and the Boston Scientific Corporation, WallFlex Biliary RX Stent System (K061231, K081733, K083374, and K083627).

4. Device Description

The WallFlex™ Biliary Transhepatic Stent System is comprised of two components: the implantable WallFlex Biliary Transhepatic stent and the delivery system.

The stent is offered uncovered or covered. The covered stents are offered as fully covered, or partially covered with a Permalume™ stent covering. The stent wires have a radiopaque core to improve radiopacity.

The stent is preloaded onto the delivery system, which has radiopaque marker bands used to aid in imaging during deployment of the stent. The delivery system accommodates a 0.035 in (0.89 mm) guidewire.

5. Indication for Use:

The WallFlex Biliary Transhepatic Stent System is indicated for use in the palliative treatment of biliary strictures produced by malignant neoplasms.

6. Technological Characteristics:

The proposed WallFlex Transhepatic Biliary Stent System has the same technological characteristics (such as the stent and delivery system dimensions, materials, and design features) as the predicate Wallstent Transhepatic Biliary Stent System (K964119), the Wallstent Biliary Endoprosthesis (K000308, K993232), and the WallFlex Biliary RX Stent System (K061231, K081733, K083374, and K083627).

The proposed device has the same intended use and is placed using the same methodology as the predicate device (Wallstent Transhepatic Biliary Stent System) via a flexible delivery system.

7. Performance Data:

Biocompatibility and performance testing was performed on the proposed WallFlex Biliary Transhepatic Stent System.

Biocompatibility Testing Summary:
The proposed stent is identical to the current WallFlex Biliary RX Stent (K061231, K081733, K083374, and K083627), and therefore no further biocompatibility testing was done on the stent. The proposed delivery system is manufactured utilizing identical materials that are used on the current predicate devices. Biocompatibility was evaluated in accordance with EN ISO 10993-1:2009, and the following tests were performed on the delivery system: Cytotoxicity, Sensitization, Irritation, Acute Systemic Toxicity, USP Physicochemical Test, and Material Mediated Rabbit Pyrogen Test.

Performance Testing Summary:
Comparative performance testing was successfully completed to establish substantial equivalence between the proposed WallFlex Biliary Transhepatic Stent System and the predicate devices. This testing included but was not limited to deployment, reconstrainment, guidewire passage, and trackability/pushability.

8. Conclusion:

All biocompatibility tests conducted on the WallFlex Biliary Transhepatic Stent System passed. Therefore, the WallFlex Biliary Transhepatic Stent System is considered biocompatible for its intended use.

All device bench test results were acceptable. The data demonstrate that the WallFlex Biliary Transhepatic Stent System sufficiently meets the design specifications and is suitable for the intended use.

Boston Scientific has demonstrated that the proposed WallFlex Biliary Transhepatic Stent System is substantially equivalent to Boston Scientific Corporations currently marketed Wallstent Biliary Transhepatic Stent System (K964119), the Wallstent Biliary Endoprosthesis (K000308, K993232), and the Boston Scientific WallFlex Biliary RX Stent System (K061231, K081733, K083374, and K083627).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Thomas Hirte
Senior Manager, Regulatory Affairs
Boston Scientific Corporation
100 Boston Scientific Way
MARLBOROUGH MA 01752

DEC 29 2011

Re: K112543
Trade/Device Name: WallFlex® Biliary Transhepatic Stent System
Regulation Number: 21 CFR §876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: FGE
Dated: December 21, 2011
Received: December 22, 2011

Dear Mr. Hirte:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

> The safety and effectiveness of this device for use in the vascular system have not been established.

Furthermore, the indication for biliary use must be prominently displayed in all labeling, including pouch, box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Christy Foreman
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K112543

Device Name: WallFlex® Biliary Transhepatic Stent System

Indications For Use: The WallFlex Biliary Transhepatic Stent System is indicated for use in the palliative treatment of biliary strictures produced by malignant neoplasms.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K112543